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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,583	09/23/2003	Guochuan Tsai	13785-745005	1550

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EXAMINER

HENLEY III, RAYMOND J

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 07/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/668,583

Applicant(s)

TSAI ET AL.

Examiner

Raymond J Henley III

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

CLAIMS 1-48 ARE PRESENTED FOR EXAMINATION

Applicants' Amendment, Terminal Disclaimer and Information Disclosure Statement filed June 25, 2004 have been received and entered into the application. Accordingly, the specification at page 1 has been amended. Also, as reflected by the attached, completed copy of form PTO-1449, the cited references have been considered.

In view of the above Amendment and Terminal Disclaimer, the objection to the specification and double patenting rejection of claims 1-48 as set forth in the previous Office action are withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 1-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cordi et al. (U.S. Patent No. 5,468,763 "Cordi '763") and Cordi et al. (U.S. Patent No. 5,061,721 "Cordi '721"), each of record (cited by Applicants on September 23, 2003) in light of applicants' acknowledgment at page 1, lines 7-8 under the heading "Background of the invention".

Cordi '763 and '721 teach a method for the treatment of Alzheimer's disease which comprises the administration of D-cycloserine as well as salts, derivatives and prodrugs thereof (See Cordi '763 at the abstract, col. 4, line 47 – col. 5, line 39; and Cordi '721 at the abstract, col. 2 "Formula (I)", col. 3, lines 17-38, col. 4, lines 13-51 and col. 10, claims 1 and 4). Pharmaceutical formulations useful in the methods are taught to be in a form useful for various routes including oral, nasal, topical, buccal, sublingual or parenteral such as subcutaneous, intramuscular, intravenous and intradermal (Cordi '763 at col. 9, lines 20-33 and Cordi '721 at col. 10, lines 40-51).

The differences between the above and the claimed subject matter lie in the patentees fail to highlight:

- (1) the presently claimed dosage amounts and treatment duration; and
- (2) the additional administration of the claimed acetylcholine esterase inhibitors and compositions comprising both a D-cycloserine compound and an acetylcholine esterase inhibitor.

However, to the skilled artisan, the claimed subject matter would have been obvious because:

- (1) Cordi '763 and '721 teach a daily dosage of from 0.1 to about 10 mg per kilogram of body weight per day which would equate to from 7 to about 700 mg per day

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for the average 70 kg adult human (see Cordi '763 at col. 9, line 7 and Cordi '721 at col. 10, lines 25-26). The determination of the optimum ingredient amounts and length of therapy would have been matter well within the purview of the skilled artisan and the artisan would have expected the dosage and therapy length to vary according to the patient's age, height, weight, tolerance to the active agent and severity of illness.

(2) Applicants' acknowledge that the claimed acetylcholine esterase inhibitors were also known to be effective in the treatment of Alzheimer's disease and it has been held that it is considered prima facie obvious to have combined two or more ingredients each of which was known to be useful for the same purpose in order to form a third composition that is useful for the very same purpose. The idea for combining them flows logically from their have been used separately. See In re Kerkhoven 205 U.S.P.Q. 1069 (CCPA 1980) and the cases cited therein. The skilled artisan would have been motivated to combine such ingredients in order to achieve at least additive results.

Accordingly, for the above reasons, the claims are deemed properly rejected.


None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Raymond J Henley III
Primary Examiner
Art Unit 1614

July 22, 2004